DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 2, 2014

Varian Medical Systems, Inc.
% Mr. Peter J. Coronado
Director, Global Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 94304

Re: K142268
Trade/Device Name: Varian Verification System (VVS)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: August 14, 2014
Received: August 15, 2014

Dear Mr. Coronado:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142268

Device Name
Varian Verification System

Indications for Use *(Describe)*

Varian Verification System is designed to assist the operator of a radiation therapy device in providing accurate treatment setups for each patient by monitoring the correct selection of patient, patient-specific accessories, conical collimator accessory and preventing the radiation treatment device from commencing irradiation when the selected patient, patient-specific accessories or conical collimator are out of conformance with the treatment plan.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Premarket Notification [510(k)] Summary

Varian Verification System

The following information is provided following the format of 21 CFR 807.92(c).

Submitter's Name:	Varian Medical Systems, Inc. 3100 Hansen Way E-110 Palo Alto, CA 94304 Contact Name: Peter J. Coronado Phone: 650.424.6320 Fax: 650.646.9200 Date: August 14, 2014
Proprietary Name:	Varian Verification System (VVS)
Classification Name:	Medical charged-particle radiation therapy system 21 CFR 892.5050, Class II Product Code: IYE
Common/Usual Name:	Varian Verification System (VVS)
Predicate Devices:	Patient Accessory Verification System (PAVS) of 4DITC – K091132 Barcode Conical Collimator Verification (BCCV) K103394
Device Description:	Varian Verification System (VVS) is a new product combining two existing products: Barcode Conical Collimator Verification (BCCV) and Patient Accessory Verification System (PAVS) under 4D Integrated Treatment Console (4DITC). With VVS the features of both BCCV and PAVS can be present, or alternatively, features of only BCCV or only PAVS. Key features include operator assistance in providing accurate treatment setups for each patient by monitoring the correct selection of patient, patient-specific accessories and conical collimator accessory. Also the system prevents the radiation treatment device from commencing irradiation when the selected patient, patient-specific accessories or conical collimator are out of conformance with the treatment plan.
Intended Use Statement	Varian Verification System is designed to assist the operator of a radiation therapy device in providing accurate treatment setups for each patient by monitoring the correct selection of patient, patient-specific accessories, conical collimator accessory and preventing the radiation treatment device from commencing irradiation when the selected patient, patient-specific accessories or conical collimator are out of conformance with the treatment plan.
Indications for Use Statement	Varian Verification System is designed to assist the operator of a radiation therapy device in providing accurate treatment setups for each patient by monitoring the correct selection of patient, patient-specific accessories, conical collimator accessory and preventing the radiation treatment device from commencing irradiation when the selected patient, patient-specific accessories or conical collimator are out of conformance with the treatment plan.

Technological Characteristics:

FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	PATIENT ACCESSORY VERIFICATION SYSTEM (PAVS) OF 4DITC	BARCODE CONICAL COLLIMATOR VERIFICATION (BCCV)	VARIAN VERIFICATION SYSTEM (VVS 1.0)
Predicate Device Clearance Number:	K091132	K103394	Not yet available
Indications for Use	The 4DITC function is designed to assist the operator of a radiation therapy device in providing accurate treatment setups for each patient by monitoring setup parameters and preventing the radiation therapy device from commencing irradiation when any parameter is out of conformance with the treatment plan.	Barcode Conical Collimator Verification is designed to assist the operator of a radiation therapy device in providing accurate treatment setups for each patient by monitoring the correct selection of a conical collimator accessory (accelerator accessory) and preventing the radiation treatment device from commencing irradiation when the selected conical collimator is out of conformance with the treatment plan.	Varian Verification System is designed to assist the operator of a radiation therapy device in providing accurate treatment setups for each patient by monitoring the correct selection of patient, patient-specific accessories, conical collimator accessory and preventing the radiation treatment device from commencing irradiation when the selected patient, patient-specific accessories or conical collimator are out of conformance with the treatment plan.
Allows users to identify accessories (not directly connected to a linac) for patient and interlock the radiation beam until these devices have been acknowledged by the end-user.	No (Conical Collimators)	Yes (Conical Collimators)	Yes (Conical Collimators)
	Yes (block, bolus, compensator)	No (block, bolus, compensator)	Yes (block, bolus, compensator)
Allows patient verification between the patient on the treatment schedule with the patient in the treatment room.	Yes	No	Yes
A hand-held bar code scanner is used in conjunction with software.	Yes	Yes	Yes
Supported Barcode Reader	Datalogic barcode reader GBT4100-BK	Datalogic barcode reader GBT4100-BK	Datalogic Gryphon 4400-HC-2D, part number 7820037470

FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	PATIENT ACCESSORY VERIFICATION SYSTEM (PAVS) OF 4DITC	BARCODE CONICAL COLLIMATOR VERIFICATION (BCCV)	VARIAN VERIFICATION SYSTEM (VVS 1.0)
User defines which accessories require a bar code label to be scanned.	Yes (block, bolus, compensator)	Yes (Conical Collimators)	Yes (Conical Collimators and block, bolus, compensator)
User staff creates the labels for the accessories using label creation software in ARIA Oncology Information System for Radiation Oncology and a label printer.	Yes (block, bolus, compensator)	No (block, bolus, compensator)	Yes (block, bolus, compensator)
	No (Conical Collimators)	No – pre-printed labels for conical collimators are provided as part of BCCV system	No – pre-printed labels for conical collimators are provided as part of VVS system
User scans the appropriate accessories for each patient's treatment field for accessory selection verification.	Yes	Yes	Yes
Support for emergency patient treatment when the treatment plan is not present in the Oncology Information System	No	No	Yes
Consoles Supported	4DITC TrueBeam Varian Treatment	4DITC TrueBeam	4DITC

Performance Data:

Software Verification and Validation Testing

Software verification and validation was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern.

Clinical Tests No clinical tests have been included in this pre-market submission

Conclusions

The non-clinical data support the safety of the device and the software verification and validation demonstrate that the VVS device performs as intended. Varian therefore considers VVS to be safe and effective and to perform at least as well as the predicate devices.